DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Brendan O Mara, Managing Director
Shannon Minerals Ltd.
Upper Clare Street
Limerick
Ireland

NOV 30
2009

Dear Mr. 0Mara:

This letter is in response to your new dietary ingredient submission to the Food and Drug Administration (FDA) dated September 19,2005, pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 350b(a)(2)). Your submission notifies FDA of your intent to market a product named "Burren Springs Trim" that contains "Extract of Garcinia Cambogia, (-)-Hydroxycitric Acid, specifically Citrin K BG®" (hereinafter "your Extract of Garcinia Cambogia"). According to your notification, your "Extract of Garcinia Cambogia" is an extract of the fruit rind of *Garcinia cambogia* [(Gaertn.)] Desr. You assert that your "Extract of Garcinia Cambogia" is a new dietary ingredient.

According to your notification, the product "Burren Springs Trim" would contain" 1400 mg of Citrin K BG®, an Extract of Garcinia Cambogia delivering 700mg of (-)-HCA [hydroxycitric acid]." This amount of your "Extract of Garcinia Cambogia" would be contained in 500 ml of water (16.9 oz) packaged in individual bottles with label directions stating, "Recommended usage of no more than 3 bottles daily" and "Caution: This product should be avoided during pregnancy, lactation and by children." Your notification states that the other ingredients of the product will be citric acid and natural flavor.

FDA has carefully considered the information in your submission. For the reasons explained below, the agency has concluded that your proposed product does not meet the definition of a dietarysupplement insection201(ff)oftheAct(21U.S.C.321(f£)). Becauseyourproductis not a dietary supplement, it is not subject to the new dietary ingredient notification requirement in section 413(a)(2) of the Act. Therefore, we have not evaluated the information you provided as the basis for your conclusion that a dietary supblement containing your "Extract of Garcinia Cambogia" will reasonably be expected to be safe.

Undersection 201(f1)(2)(B)oftheAct(21U.S.C. 321(f1)(2)(B)),theterm"dietary supplement" means a product that, among other requirements, "is not represented for use as a conventional food or as a sole item of a meal or the diet." "Burren Springs Trim" is represented as conventional food because of its packaging and the volume in which it is intended to be consumed. The product is sold in a 500 ml bottle, and the directions for use recommend a daily intake of up to 3 bottles a day, for a total fluid intake of 1500 milliliters (ml) per day (51 oz). Based on data from the 2005-06 National Health and Nutrition Examination Survey (NHANES) on daily intake of drinking water and other beverages in the United States, FDA estimates the average total daily drinking fluid intake per person to be about 1.2 liters (1200 ml)? The 1.5 liter maximum recommended daily intake of your product thus exceeds the total daily drinking fluid intake of an average person in the U.S. In addition, the proposed packaging for the product, which is a bottle similar to the kind of bottle in which single servings of beverages like soda, bottled water, and iced tea are sold, suggests that the product is intended for use as a beverage. Beverages are conventional foods. Accordingly, the product's proposed packaging, serving size, and recommended conditions of use represent it as a conventional food, rather than as a product intended to supplement the diet. Therefore, "Burren Springs Trim" is excluded from the dietary supplement definition undersection201(f1)(2)(B)oftheActandmaynotbemarketed asadietarysupplement.

Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than the requirements that apply to dietary supplements. Among other things, the product must bear nutrition labeling in accordance with Title 21 of the Code of Federal Regulations (21 CFR 101.9), ingredient labeling in accordance with 21 CFR *IOIA,* and a statement of identity in accordance with 21 CFR 101.3. Additionally, under the Act, any substance that is intentionally added to a food is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive (e.g., color additive). See 21 V.S.C. 321(s),

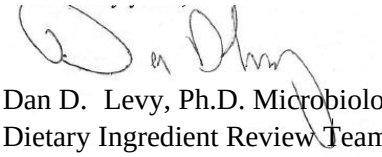
348. If you intend to market this product as a conventional food and have any questions about the status of any of its ingredients, please contact FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

[1] "Drinking fluid intake" means total fluid intake from tap water, bottled water, and other beverages. It excludes fluid intake from foods (e.g., soups, sauces, etc.).

[2] Foods Analysis and Residue Evaluation Program (FARE), Version 8.50, Consumption Analysis: Distribution and Means Analysis based on NHANES 2005-2006.

If you have any questions concerning this matter please contact Dr. Fred Hines, the Consumer Safety Officer for the New Dietary Ingredient Review Team, at (301) 436-1756.

Sincerely Yours,



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